INITIAL STATEMENT OF REASONS AND PUBLIC REPORT
DEPARTMENT OF PESTICIDE REGULATION

Title 3. California Code of Regulations
Repeal and Readopt Sections 6450,
Adopt Sections 6450.1, 6450.2, 6450.3, and
Amend Sections 6000 and 6784
Pertaining to Methyl Bromide Field Fumigation

This is the Initial Statement of Reasons required by Government Code section 11346.2 and the public report specified in section 6110 of Title 3, California Code of Regulations (3 CCR). Section 6110 meets the requirements of Title 14 CCR section 15252 and Public Resources Code section 21080.5 pertaining to certified state regulatory programs under the California Environmental Quality Act.

SUMMARY OF PROPOSED ACTION/PESTICIDE REGULATORY PROGRAM ACTIVITIES AFFECTED

The Department of Pesticide Regulation (DPR) proposes to repeal and readopt sections 6450, adopt sections 6450.1, 6450.2, 6450.3, and amend sections 6000 and 6784 of 3 CCR. The pesticide regulatory program activities that will be affected by the proposal are those pertaining to restricted materials. In summary, the proposed action would permanently adopt methyl bromide field fumigation regulations focusing on mitigating possible acute and subchronic methyl bromide exposure hazards to the public and agricultural employees.

DPR adopted permanent methyl bromide field fumigation regulations that became effective on January 14, 2001. DPR then adopted amendments to these regulations on April 8, 2002. However, the regulations were voided by a recent court decision (*Ventura County Agricultural Association vs. DPR*) on the grounds that DPR did not adequately consult with the California Department of Food and Agriculture (CDFA) prior to noticing the regulations. DPR filed emergency regulations to repeal and readopt these regulations since it was necessary to maintain continuity and to ensure continued protection of the health and safety of workers and the public when methyl bromide is used for field fumigation. The emergency regulations became effective on September 22, 2002. While DPR reviewed new data and consulted with other agencies, some of which was required pursuant to a settlement agreement in *Carrillo vs. DPR*, subsequent emergency regulations were refiled with OAL (effective on January 9, 2003, and May 21, 2003). The proposed regulatory action would make permanent methyl bromide field fumigation regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS

Methyl bromide is a pesticide commonly used in agriculture. Methyl bromide is a gaseous fumigant used to treat soil before planting vegetable, fruit and nut crops, and flower and forest nurseries. Depending on the crop, field applications may occur annually or once every several years. Methyl bromide is injected into the soil with specialized application equipment that lays tarpaulins over the ground to minimize off-gassing for several days. Methyl bromide is also used

in other settings not covered by this rulemaking action. For example, after harvest, methyl bromide fumigation is used to protect crops from pest damage during storage and transportation. The fumigant is also used for quarantine pest control; termite eradication in homes and other structures; and to control insects in mills, ships, railroad cars, and other transportation vehicles.

Methyl bromide exposure may produce harmful effects on people. Exposure results from inhalation or absorption through the skin. Despite its potential to cause harmful effects to humans, methyl bromide still remains one of the most widely used pesticides in the world due to its outstanding efficacy against a broad range of pests and the lack of effective alternatives.

Methyl bromide is listed as a restricted material in 3 CCR section 6400(d). Possession and use of methyl bromide for agricultural production purposes are allowed only under a restricted materials permit from the local county agricultural commissioner (CAC). Before issuing a permit, the CAC must evaluate the permit application to determine whether the intended use may cause a substantial adverse environmental impact based on local conditions at the application site. Depending on the results of this review, the CAC may deny the permit or impose permit conditions including the use of specified mitigation measures. In evaluating permit applications, CACs consider and, where appropriate, use information provided by DPR. For methyl bromide, DPR provides this information as suggested permit conditions. The suggested permit conditions provide mitigation measures the CAC can use and are based on DPR's analysis of available data. CACs can impose more stringent mitigation measures than in the suggested permit conditions based on the local conditions at the application site.

In 3 CCR, there are regulations pertaining to the field fumigation use of methyl bromide. In late December 2000, DPR adopted regulations focused upon mitigating possible acute (short-term) methyl bromide exposure hazards to the public and agricultural employees. Suggested permit conditions formed the foundation upon which the regulations were based.

DPR had determined that many of the suggested permit conditions existing at that time needed to be incorporated into regulation for use of methyl bromide as a field fumigant. This was due to a number of factors. First, under the Birth Defect Prevention Act of 1984, DPR required additional health effects studies to be performed on methyl bromide and many other pesticides. DPR also had completed a risk assessment for methyl bromide. Methyl bromide causes a variety of health effects in experimental animals and humans. To evaluate health risks, DPR scientists calculated target concentrations based on the toxicity of methyl bromide in experimental animals, and compared the target concentrations to the monitoring data. When data from animal studies are used to determine a margin of exposure (MOE), the target concentration is generally 100 times lower than the lowest dose that does not cause adverse effects (the no-observed-effect level [NOEL]) in animal studies. The 100-fold factor accounts for variation in sensitivity between individuals, and assumes that people are more sensitive than experimental animals to the effects of methyl bromide. This risk assessment is contained in a 466-page document entitled *Methyl Bromide Risk Characterization Document For Inhalation Exposure (draft)*(DPR, 1999)

and is listed in the "Documents Relied Upon" section of this Initial Statement of Reasons. This risk characterization document (RCD) was peer-reviewed by the U.S. Environmental Protection Agency (U.S. EPA), California's Office of Environmental Health Hazard Assessment, and the National Academy of Sciences (NAS).

On May 19, 2000, DPR held a workshop with stakeholders to discuss the NAS peer review. Also participating were members of the National Research Council (NRC) subcommittee who conducted the peer review. Although the peer review is often referred to as the "NAS peer review," a subcommittee of the NRC--the principal operating agency of the NAS and National Academy of Engineering in providing services to the government, the public, and the scientific and engineering communities--conducted the peer review. The document itself is identified on the cover as a report of the NRC. Because of the intense interest generated by the peer review, DPR felt that a workshop would be an ideal opportunity to allow public discussion of the subcommittee's findings and recommendations. At the workshop, scientists from both the NRC subcommittee and DPR discussed the peer review as well as the conclusions and recommendations contained within it.

The regulations DPR adopted in December 2000 also incorporated DPR's refined computer models for estimating methyl bromide emissions. When suggested permit conditions were first issued, about a dozen air monitoring studies were available. The new models incorporated more than 40 air monitoring studies. The Air Resources Board (ARB) reviewed DPR's dispersion modeling that was conducted to develop buffer zones around methyl bromide soil fumigations. The University of California at Berkeley conducted a peer review of the exposure mitigation component of the proposed regulations; specifically, the computer modeling procedures used to establish buffer zone distances. The University of California at Riverside reviewed DPR documents "Summary of Off-site Air Monitoring For Methyl Bromide Field Fumigations," "Recommendations for Methyl Bromide Buffer Zones for Field Fumigations," "Evaluation of Charcoal Tube and SUMMA Canister Recoveries from Methyl Bromide Air Sampling," and the text of the proposed regulations. The University of California at Los Angeles reviewed DPR documents "Recommendations for Methyl Bromide Buffer Zones for Field Fumigations" and "Summary of Off-site Air Monitoring for Methyl Bromide Field Fumigations."

Incorporating some of the suggested permit conditions into the December 2000 regulations allowed DPR to meet two important goals. First, it ensured the uniform enforcement of methyl bromide use practices. Statewide directives need to be consistent and unambiguous, yet allow CACs to issue permits using sound science and application specific information. Second, the regulation adoption process allowed the public to have a voice in developing the final regulations that pertain to field fumigation use of methyl bromide. DPR held four public hearings and received over 800 comments during the public comment periods provided. Many changes to the originally proposed text were made as a result of the comments received.

DPR faced a stringent timeframe for adoption of the regulations in December 2000. A San Francisco Superior Court decision in 1999 ruled that Food and Agricultural Code (FAC) section 14081 required DPR to adopt regulations on field fumigation use for methyl bromide. The Court imposed a June 1, 2000, deadline for submission of the amended regulations to the Office of Administrative Law (OAL). This deadline was later extended.

The regulatory action amended sections 6000 (Definitions), 6450 (Chloropicrin and Methyl Bromide-Field Fumigation) and 6784 (Field Fumigation), and added sections 6450.1 (Notification Requirements), 6450.2 (Buffer Zone Requirements), and 6450.3 (Fumigation Methods). In addition to amending use restrictions and general safe-use requirements for field fumigations, new provisions that were not contained in suggested permit conditions were added. These provisions include submission of a work site plan at the time a property operator applies for a restricted materials permit, notification to neighboring property operators prior to a fumigation, extra protection for children in schools, establishment of minimum buffer zones, and new limits on work hours for fumigation employees. OAL approved the regulations adopted in December 2000, and they became effective on January 14, 2001.

DPR subsequently adopted methyl bromide field fumigation emergency regulations on June 27, 2001, to amend sections 6450.2 and 6450.3(a)(1)(C)2 to provide an immediate and effective mechanism to implement appropriate mitigation measures to protect workers from acute methyl bromide exposure hazards. The regulations that became effective on January 14, 2001, had prohibited inner buffer zones from extending onto public roadways. However, DPR determined the minimal methyl bromide exposure to people traveling along roads did not warrant the restrictions. The impact of this restriction resulted in agricultural acreage being divided into smaller application blocks to be treated over several days over a longer period of time. By increasing the number of field fumigations, fumigation handlers were potentially at greater risk of acute methyl bromide exposure hazards due to the increased need to disassemble application equipment prior to transporting the equipment to the next application site. The emergency regulations allowed the inner buffer zone to extend into public roadways upon commissioner approval and corrected an improper application equipment configuration. The emergency regulations were readopted on October 25, 2001.

On February 22, 2002, DPR filed the certificate of compliance with OAL to make the emergency regulations permanent. These regulations became effective on April 8, 2002. That regulatory action also amended section 6784(b) exempting employees involved in fumigation-handling activities from maximum work-hour restrictions if National Institute for Occupational Safety and Health (NIOSH)-certified respiratory protection specifically recommended for use in atmospheres containing less than five parts per million (ppm) methyl bromide is worn for the entire duration of the fumigation-handling activities. Like the regulations that became effective on January 14, 2001, these regulations focused on mitigating possible acute (short-term) methyl bromide exposure hazards to the public and agricultural employees.

In early 2001, the Ventura County Agricultural Association filed a lawsuit against DPR arguing that DPR did not consult adequately with CDFA, as required by law, during the development of the methyl bromide field fumigation regulations, which became effective on January 14, 2001. Also, a separate lawsuit by the Environmental Defense Center et al., also challenged the methyl bromide regulations on a variety of issues. The lawsuits were later consolidated.

On April 8, 2002, San Francisco Superior Court Judge James Robertson rendered a decision on the two consolidated lawsuits filed against DPR. The judge ruled that DPR did not adequately consult with CDFA on the development of the regulations, and, in his order, the judge voided the regulations. However, he issued a 45-day stay to allow the Department to "consider implementing replacement regulations, in such a form as DPR deems appropriate." The judge declined to rule on the claims of the Environmental Defense Center et al., lawsuit "on the grounds that they are moot." A copy of the judge's order is listed in the "Documents Relied Upon" section of this Initial Statement of Reasons.

Although DPR disagreed with the judge's ruling that it failed to consult adequately with CDFA before finalizing the methyl bromide regulations that became effective on January 14, 2001, in the interest of expediency, DPR decided not to appeal the ruling.

In staying the order for 45 days, the Court recognized the importance of continuing the regulatory program through emergency regulations. On May 10, 2002, DPR filed such emergency regulations with OAL (OAL File No. 02-0519-02E). After the emergency regulations were filed, however, the Ventura County Agricultural Association requested that DPR consider extending the stay of the Court's order for an additional 120 days. DPR had no objection to extending the stay and agreed to an extension. Consequently, on May 20, 2002, DPR withdrew the emergency regulations.

On May 14, 2002, under the settlement agreement in a separate lawsuit *Carrillo vs. DPR and Monterey County Agricultural Commissioner,* DPR agreed to review and consider the regulation of subchronic methyl bromide exposure when repromulgating the methyl bromide field fumigation regulations. The repromulgation would be needed because of the *Ventura County Agricultural Association* case, which voided the existing regulations. Because of the additional review and consultation duties that resulted from the *Carrillo* case settlement agreement, DPR filed emergency regulations with OAL (OAL File No. 02-0910-01E) before the stay expired on September 23, 2002. The emergency regulations became effective on September 22, 2002. DPR readopted the emergency regulations (OAL File No. 03-0109-01EE), which became effective on January 21, 2003, as additional air monitoring results from the 2001 use season and new subchronic toxicity studies that potentially could be used to support the permanent regulations were under review.

As mentioned above, DPR conducted risk assessments to address the potential risk associated with human exposure to methyl bromide in California. After peer reviewing the draft *Methyl*

Bromide RCD (DPR, 1999), the NRC subcommittee recommended additional studies, in particular a new subchronic toxicity study, and exposure monitoring to better characterize the risk. In 2002, DPR finalized the *Methyl Bromide Risk Characterization Document For Inhalation Exposure* (DPR, 2002) in response to the recommendations made by NRC. It included the data from ambient air monitoring conducted in several counties in 2000 and 2001 during high use periods. Further, DPR staff prepared a document entitled *Methyl Bromide Risk Characterization Document For Inhalation Exposure Addendum to Volume I* (DPR, 2003), which is an addendum to the completed risk assessment and reviews all data received to date, including a newly submitted subchronic toxicity study. The newly submitted study was reviewed by scientists from the University of California, as well as DPR scientists.

After completion of the addendum, on February 26, 2003, DPR held a public workshop to present staff analysis on subchronic exposure levels to methyl bromide. DPR solicited public comments on an appropriate target value for subchronic exposures. After the workshop, DPR requested an additional toxicology review from U.S. EPA. After consideration of all the comments and reviews, DPR scientists have recommended the subchronic exposure target levels of 16 parts per billion (ppb) for adults, and 9 ppb for children. These target levels will provide an adequate margin of safety for human subchronic exposure to methyl bromide. The DPR target level for acute exposure is 210 ppb (24-hour time-weighted average)--the same target level used to develop the current emergency methyl bromide field fumigation regulations. (The documents used to support the current regulations refer to the concentration level of 0.21 ppm. The 0.21 ppm level is equivalent to 210 ppb, and will hereafter be referred to as 210 ppb).

In addition to the toxicology study evaluations, DPR staff analyzed the 2000 and 2001 methyl bromide air monitoring data, and established some empirical relationships between the ambient air concentration and the field fumigation use of methyl bromide in certain areas and periods. The document is entitled *Calculation of a Tolerance Interval for a Township Limit on Methyl Bromide Use to Control Subchronic Exposure* and is listed in the "Documents Relied Upon" section of this Initial Statement of Reasons. The air monitoring and DPR's analysis were discussed at a public workshop on June 28, 2002.

DPR consulted with other state agencies, air pollution control districts, CACs, and the University of California to determine if mitigation measures should be considered to protect the public and agricultural employees from possible subchronic methyl bromide exposure hazards. Because of this extensive review and consultation process, some of which is required pursuant to the settlement agreement in the *Carrillo* case, it was necessary for DPR to readopt the emergency regulations that are the currently in effect. The readopted emergency regulations became effective on May 21, 2003.

The high use period for methyl bromide in California occurs from August to October. During the largest portion of this high use "season," it is anticipated that agricultural workers may work five to seven days per week over a four-to-five week period (approximately one month). This

exposure scenario extends well beyond what would normally be considered acute and is significantly less than what is typically considered annual (chronic) exposure. DPR refers to this exposure scenario as intermediate-term exposure (subchronic), and it is sometimes referred to as "seasonal" exposure. DPR assumes that subchronic exposure is continuous. This one-month intermediate-term exposure was compared to subchronic toxicity data for consideration of potential toxicological impacts. For exposure periods beyond one month, it is assumed that the exposures would be intermittent rather than continuous.

The proposed action would permanently adopt methyl bromide field fumigation regulations focusing on mitigating possible acute and subchronic methyl bromide exposure hazards to the public and agricultural employees. A discussion of each section of the proposed text is found below. As mentioned previously in this Initial Statement of Reasons, DPR intends to repeal the existing text of each section--or portion of section in the case of section 6000--and then readopt regulations. In the following discussion, references are made to "old suggested permit conditions." This means the suggested permit conditions that were in effect in January 2000, when DPR proposed its new methyl bromide field fumigation regulations (which became effective in January 2001). Those "old suggested permit conditions" were later updated after adoption of the new regulations. The new permit conditions document is entitled "The Guidance Manual: Methyl Bromide (In Combination With Chloropicrin) - Field Soil Fumigation" and is listed in the "Documents Relied Upon" section of this Initial Statement of Reasons.

6000. Definitions.

This section contains proposed definitions for "application block" and "buffer zone." These definitions are needed for the proposed regulatory action. "Application block" means a field or portion of a field treated in a 24-hour period that typically is identified by visible indicators, maps, or other tangible means. A "buffer zone," as used in sections 6450, 6450.1, and 6450.2, is the area that surrounds a pesticide application block in which certain activities are restricted for a specified period of time to protect human health and safety from existing or potential adverse effects associated with a pesticide application.

6450. Chloropicrin and Methyl Bromide-Field Fumigation.

Methyl bromide may be used singly or in combination with chloropicrin or other pesticides. These regulations pertain to field soil fumigation use requirements using methyl bromide and are intended to mitigate exposures to methyl bromide used during field fumigations.

In the introductory paragraph of proposed section 6450, DPR clarifies that for the purposes of this section, field fumigation does not apply to golf courses, tree holes, potting soil, greenhouses, and other similar structures. The proposed regulatory action focuses upon preplant field soil fumigations pertaining to the production of agricultural commodities. Greenhouse, golf course, potting soil, tree hole fumigations, and raised-tarpaulin nursery fumigations of less than one acre

may be addressed in future regulatory actions. In addition, since the definition for "field" in section 6000 includes greenhouses, this statement is needed for consistency.

Proposed section 6450 clarifies and defines certain employee tasks that are considered "fumigation handling activities." This means employees involved in, but not limited to, assisting with covering the tarpaulin at the end of the rows (shoveling); assisting with the overall operation, ensuring proper tarpaulin placement and condition, changing cylinders (copiloting); operating application equipment (driving); tarpaulin cutting; and tarpaulin removal prior to the expiration of the restricted entry interval. The phrase, "… prior to the expiration of the restricted entry interval" was added to the text to clarify that employees removing the tarpaulin after the expiration of the restricted entry interval are no longer considered fumigation handlers. The description of fumigation handling activities, currently located in section 6784(b)(1), is being relocated to help clarify references made in proposed sections 6450 and 6450.2.

Proposed subsection (a) pertains to a proposed work site plan. The operator of the property where the fumigation will take place shall provide a proposed work site plan to the CAC for evaluation at least seven days prior to submitting a notice of intent. Subsection (a) specifies what is to be included in the proposed work site plan and that the plan shall be retained by the CAC for one year after permit expiration. The work site plan must include method of application to be used, acreage, and identification of each application block, application rate, description of the notification procedure to property operators pursuant to section 6450.1(b), description of any activities within the buffer zone(s) as specified in section 6450.2(e) and (f), description of any workday and work hour limitations and respiratory protection as specified in section 6784(b)(3) and (6), and if applicable, a description of the tarpaulin repair response plan and tarpaulin removal. DPR has not prescribed a particular form to be used for the work site plan, although sample formats are available from DPR. CACs will be allowed to custom-tailor their own work site plan forms in a manner that addresses local issues and in a format that works best for their county. Some counties already do this and prefer to retain this flexibility.

Proposed subsection (b) states that the CAC, pursuant to section 6432 (Permit Evaluation), shall evaluate local conditions and the proposed work site plan.

Proposed subsection (c) specifies the information CACs shall include when "conditioning" a permit. The permit conditions shall include buffer zone requirements, work-hour restrictions, notification requirements, any other restrictions to address local conditions, and if applicable, a description of the tarpaulin repair response plan and tarpaulin removal. The CAC evaluation and conditioning of the permit is to be completed before the permittee submits a notice of intent.

Proposed subsection (d) limits the size of an application block to 40 acres. DPR chose the 40-acre limit because it is the largest field size for which monitoring data is available.

Proposed subsection (e) specifies permeability factors for tarpaulins used in fumigations.

Permeability factors were contained in the old suggested permit conditions on page 11 under "IV. Application Requirements." In the suggested permit conditions, "high barrier" tarpaulins were limited to a permeability factor of less than 8 milliliters methyl bromide per hour, per square meter, per 1,000 ppm of methyl bromide under tarpaulin at 30 degrees Celsius. DPR's limit of between 5 and 8 milliliters methyl bromide per hour, per square meter, per 1,000 ppm of methyl bromide under tarpaulin at 30 degrees Celsius was determined by DPR scientists based upon laboratory tests and field monitoring data. Tarpaulins meeting these gas-retention standards are added to a list of DPR-approved tarpaulins maintained by the Department. This list is available from DPR. A more detailed discussion of field monitoring data pertaining to tarpaulins is found in *Summary of Off-Site Air Monitoring for Methyl Bromide Field Fumigations*. This document is listed in the "Documents Relied Upon" section of this Initial Statement of Reasons and is also available from DPR.

Proposed subsection (f) requires that tarpaulins shall remain in place for the time specified in proposed section 6450.3. This retention time will also help mitigate methyl bromide exposure to workers.

Proposed subsection (g) specifies that fumigation equipment is to be operated to eliminate pesticide drip by clearing the fumigant from the injection device before it is lifted from the soil.

Proposed subsection (h) would limit the amount of methyl bromide used in any township in any calendar month to 270,000 pounds. Ambient air monitoring was conducted in high-use areas during high-use periods. The monitoring locations and periods covered the townships and months with the top use intensity. The air monitoring captured the heaviest use scenarios in the state in 2001. Township-monthly use levels of methyl bromide were estimated, which corresponded to various subchronic air exposure reference levels. These calculations were based on an empirical relationship between ambient air concentration and use in surrounding areas. This mitigation measure would prevent air levels from exceeding the reference concentrations, reducing any potential subchronic methyl bromide exposure hazards to the public including children. However, no township had a monthly use level that led to 9 ppb air concentration level in 2001. Derivation of the township limit is described in *Calculation of a Tolerance Interval for a Township Limit on Methyl Bromide Use to Control Subchronic Exposure* and *Evaluation of Ambient Air Monitoring and Township-Month Use Pound Distribution of Methyl Bromide for Subchronic Exposure Assessment.* These documents, are listed in the "Documents Relied Upon" section of this Initial Statement of Reasons.

<u>6450.1. Methyl Bromide Field Fumigation Notification Requirements.</u>

The old suggested permit conditions contained the topic "Notice of Intent Modification" on pages 9 and 10. As discussed on those pages, a permit holder must currently notify the local CAC at

least 24 hours prior to a fumigation of any application block with methyl bromide. The CAC has the option of reducing this 24-hour notice of intent in some situations.

Proposed section 6450.1 incorporates into regulation specific notification requirements pertaining to methyl bromide field fumigations.

Proposed subsection (a), "Notification to the Commissioner," specifies what information a permit holder must provide to the CAC and when it must be provided. Currently, section 6434 (Notice of Intent), subsection (b) requires the permittee to provide certain information to the CAC 24 hours prior to the use of a pesticide requiring a permit. The proposed regulatory action will require a permittee to notify the CAC at least 48 hours prior to fumigating a property and provide the hour the fumigation is intended to commence along with the information specified in section 6434(b). Some CACs required a longer notice of intent (NOI) time frame prior to methyl bromide fumigation even prior to the adoption of the regulations. It enabled them to have more time to review the permit and do preapplication inspections. Subsection (a) also requires that a new NOI be submitted to the CAC if the fumigation does not commence within 12 hours of the intended starting time specified on the original NOI. However, the 48-hour requirement does not apply unless required by the CAC. In addition, this subsection contains notification provisions for multiple application blocks that are to be fumigated sequentially.

Proposed subsection (b) is entitled "Notification to Property Operators." Subsection (b) requires the operator of the property to be treated to assure that operators of specified properties within 300 feet from the outer buffer zone perimeter are notified that a permit has been issued by the CAC.

The 300-foot notification distance is beyond the perimeter of the outer buffer zone. The 300-foot notification distance was selected as the distance to trigger notification of nearby property operators because DPR believes it is a reasonable distance without being overly burdensome to property operators intending to conduct fumigation activities. Also, there is regulatory consistency because a 300-foot distance is currently the regulatory distance requirement for property operators to give notification to persons who are located within that distance of a treatment site in timberland when phenoxy pesticides are to be used. See 3 CCR section 6443. The purpose of the 300-foot distance requirement is to provide an opportunity to persons who reside in proximity to an intended fumigation site to receive notification that a restricted material permit has been issued to use methyl bromide on a fumigation site near their property. Also, it is intended to give those persons the opportunity to further request specific notification of the date and time of the actual fumigation. These persons can take whatever appropriate action they wish.

DPR feels that subsection (b) provides adequate notification to persons on nearby properties, who, for whatever reason, are sensitive about the issue of methyl bromide fumigation. They will be given information about the proposed fumigation, have ample opportunity to make further inquiries, and, if desired, arrange to be out of the area during the time of the fumigation.

The specified properties are those that contain schools, residences, hospitals, convalescent homes, onsite employee housing, or other similar sites identified by the CAC.

Notification shall be in writing, or by other means approved by the CAC. The operator of the property to be treated shall assure that notification is delivered at least seven days prior to the submission of the notice of intent. This ensures that nearby property operators specified in this subsection will have at least seven days advance notice of a planned fumigation before the NOI is submitted to the CAC. This seven-day period added to the 48-hour NOI time frame provides for a total of at least nine days before a fumigation can take place. The content of the notification is to include the name of the chemical(s) to be applied, the name, business address, and telephone number for both the operator of the property to be treated and local CAC, the earliest and latest dates that the fumigation will start, and how to request subsequent notification of the specific date and time of the fumigation.

For the notified persons that subsequently request specific fumigation information, the operator of the property to be treated shall provide it to them at least 48 hours prior to starting the fumigation. If a request for specific notification is received after the submission of the NOI and before the fumigation begins, the specific fumigation notification shall be provided prior to starting the fumigation, but the 48-hour requirement shall not apply.

A notification scenario would proceed like this. The commissioner may issue a permit to use methyl bromide at any time of the year as long as it is at least nine days prior to the start of the fumigation (or seven days prior to submission of the NOI). At least nine days prior to the fumigation--assuming the permit has been issued, the work site plan submitted, and the buffer zones approved by the CAC--the operator of the property to be treated must complete the required notification. Then at least 48 hours prior to the start of the fumigation, the operator of the property to be treated must (1) re-notify those people who, within the seven-day period, requested notification of the specific date and time of the fumigation, and (2) submit a notice of intent to the commissioner.

6450.2 Methyl Bromide Field Fumigation Buffer Zone Requirements.

As proposed in section 6000, a buffer zone is the area that surrounds a pesticide application block in which certain activities are restricted to protect human health and safety from existing or potential adverse effects associated with a pesticide application. A buffer zone is not an exclusion zone in which all entry is prohibited.

Proposed section 6450.2 incorporates into regulation specific information pertaining to buffer zones. Buffer zone sizes, measurement, and duration are currently covered in the suggested permit conditions. This section establishes minimum buffer zone distances and duration, limits activities that can occur in a buffer zone, and includes special protections for schools.

DPR's buffer zone distances are set so that methyl bromide air concentrations measured at those distances from the edge of a fumigation block should not exceed 210 ppb. This level is 100 times lower than the NOELs established by DPR in its risk characterization for methyl bromide. DPR has determined that the 210 ppb concentration level provides an adequate margin of safety. Buffer zone sizes, measurement, and duration for each application method have been determined from both data received and evaluated by DPR and the results of air monitoring studies conducted by DPR scientists. DPR data shows that, in some limited cases, the 210 ppb limit is not exceeded even with no buffer zones in place. However, DPR feels that minimum buffer zone sizes and durations to provide a measure of protection against possible variations in methyl bromide air concentrations that could occur.

Methyl bromide air concentrations depend on a large number of factors such as the application rate, number of acres treated, the method of application, wind speed, wind direction, temperature, atmospheric stability, topography, field preparation procedures, soil amendments, soil type, and soil moisture. Many of these factors vary greatly with location. Therefore, in addition to the minimum buffer zones, the CAC should consider local conditions at the application site when evaluating applications for permits to use methyl bromide for field fumigations.

Proposed subsection (a) states that the CAC shall approve buffer zone sizes and durations based upon local conditions. The commissioner shall rely upon the information provided in *Methyl Bromide Field Fumigation Buffer Zone Determination, Est. 6/03*, which will be incorporated by reference, to condition restricted material permits unless the commissioner determines, based on other information, that deviation from the information provided can be made in a way that assures equal or less exposure. The commissioner shall consult with the Director prior to approving any deviation resulting in buffer zone sizes or durations less than specified in the *Methyl Bromide Field Fumigation Buffer Zone Determination, Est. 6/03.* At no time shall the inner buffer zone be less than 50 feet, and the outer buffer zone be less than 60 feet, or the buffer zone durations be less than 36 hours.

DPR uses regulations to set statewide requirements. CACs use restricted materials permits to establish local requirements, in addition to the regulations. Pursuant to FAC section 14004, DPR and the CACs enforce California's restricted materials laws and regulations. Under FAC section 14006.5, CACs have authority to issue restricted materials permits covering the use of methyl bromide and are required to consider local conditions when doing so. DPR's intent is to adopt regulations which CACs can supplement with permit requirements addressing local conditions. What may be appropriate for a field fumigation in rural Shasta County, for example, would most likely not be suitable for a coastal community in Ventura County. Therefore, if a CAC has information that can assure equal or less exposure of the target of 210 ppb, and after consultation with the Director, he may condition a permit deviating from the buffer zone sizes and durations in *Methyl Bromide Field Fumigation Buffer Zone Determination.*

Proposed subsection (b) specifies how a buffer zone shall be measured. Buffer zone distances are measured from the perimeter of the application block.

Proposed subsection (c) states that buffer zones shall begin at the start of fumigation. The buffer zone restrictions shall remain in effect for at least 36 hours after the completion of the injection to the application block.

Monitoring data show the time a buffer zone is needed varies with the application method and the amount of methyl bromide applied to the field. Therefore, DPR has developed a series of tables, in *Methyl Bromide Field Fumigation Buffer Zone Determination*, that specifies the buffer zone duration as a function of application method and amount of methyl bromide. Since this procedure is very similar to the one used to determine the buffer zone distance, DPR has proposed parallel requirements. The regulations require a minimum buffer duration of 36 hours following the end of the fumigation. CACs will determine the site specific buffer zone duration using the information provided and condition the restricted materials permit. This will ensure, at a minimum, the buffer zone restrictions are in effect during the entire application period and during the time of greatest off-gassing following the treatment.

A more detailed discussion of buffer zones and their determination is contained in *Recommendations for Methyl Bromide Buffer Zones for Field Fumigations and Workbook for Gaussian Modeling Analysis of Air Concentration Measurements*. These documents are listed in the "Documents Relied Upon" section of this Initial Statement of Reasons and are available from DPR.

Proposed subsection (d) specifies two buffer zones--an inner and outer--to be determined by the CAC after the proposed work site plan is submitted. These zones can be visualized as concentric rings around an application block.

The CAC is to follow a specific procedure for determination of buffer zone sizes. Buffer zone sizes are calculated using computer modeling procedures that have been approved by DPR, and have undergone scientific peer review.

Proposed subsection (e), entitled "Inner Buffer Zone Restrictions," specifies that an inner buffer zone shall be at least 50 feet. Activities in an inner buffer zone are limited to fumigation handling activities and transit through the zone.

An inner buffer zone shall be at least 50 feet and shall not extend into adjoining property unless certain requirements are met. The property must be an agricultural property, the adjoining property operator must give written permission, and allow the operator of the property to be treated to post the inner buffer zone on the adjoining property with signs. With approval from the CAC, the inner buffer zone may extend across sites only where transit activities may occur, including streets, roads, roads within agricultural property, highways, and other similar means of

travel. If the CAC is not convinced that possible access by road crews and utility workers will not be a problem, he/she can disapprove the extension of the inner buffer zone across the site.

DPR's regulations that became effective on January 14, 2001, required that the property must be an agricultural property, the adjoining property operator must give written permission, and allow the operator of the property to be treated to post the inner buffer zone on the adjoining property with signs. This precluded the inner buffer zone from extending into public roadways.

Since then, applicators have had to divide agricultural acreage into smaller application blocks to be treated over several days. Fumigations could take much longer to complete than they did in previous years since applicators must accommodate the new, larger buffer zones by limiting treatment to smaller application blocks. DPR has been informed of increases in number of applications ranging from 10 to 30 percent. This increases the number of times workers must transport methyl bromide to complete an application. Fumigation handlers were potentially at greater risk of acute methyl bromide exposure hazards from the increased frequency at which application equipment requires handling and disassembling prior to transport. In addition, fumigation handlers were potentially at greater risk of accidents on public roads because of the increase in the number of trips to and from individual fields.

The original intent of the inner buffer zone was to avoid exposure above the target concentration level of 210 ppb average during a 24-hour period. Prohibiting the extension of the inner buffer zone onto public roadways did not measurably reduce risks to roadway users. However, this prohibition did increase the potential risks to workers from acute methyl bromide exposure hazards. DPR concluded that there was potentially a greater exposure risk to workers from the increase in fumigations. Therefore, DPR amended these regulations to allow--with CAC approval--the inner buffer zone to extend across sites only where transit activities may occur, including streets, roads, roads within agricultural property, highways, and other similar means of travel. This would further reduce potential exposure to workers. These amendments became effective on April 8, 2002.

Proposed subsection (f), entitled "Outer Buffer Zone Restrictions" specifies that an outer buffer zone shall be at least 60 feet. Only fumigation handling, transit, and CAC-approved activities are allowed in an outer buffer zone while it is in effect. CAC-approved outer buffer zone activities must be identified in the restricted material permit conditions and cannot exceed 12 hours in a 24-hour period. The outer buffer zone may extend into adjoining property with the permission of the adjoining property operator.

The outer buffer zone may extend into other properties with permission from the operators of these other properties. In no instances shall the outer buffer zone contain occupied residences or occupied onsite employee housing while the outer buffer zone is in effect. The outer buffer zone shall not extend into properties that contain schools, convalescent homes, hospitals, or other

similar sites determined by the CAC. The outer buffer zone may extend across roads, highways, or similar means of travel or sites approved by the CAC.

Proposed subsection (g) requires the operator of the property to be treated shall assure that the operator of the other specified properties into which a buffer zone may extend notify onsite employees, including those of a licensed pest control business or farm labor contractor, that a buffer zone(s) has been established on the property. The notice to employees shall be given prior to the commencement of the employee's work activity. Notification to farm labor contractor employees may be done by giving written notice to the farm labor contractor, who shall then give the notice to the employee. Employee notification shall include information required in section 6450.1(b)(2).

DPR has not specified an advance timeframe, such as 24 hours, for this notification. Workers may not be available to be informed 24 hours prior to fumigation and any worker reporting to work that was not informed 24 hours ahead of time would either not be allowed to work that day or the fumigation would have to be postponed. Such a requirement could place an unwarranted burden on both the other property operator and his/her employees, especially if the services of a labor contractor are utilized. Notifying and accommodating newly hired employees and employees that have been absent from work (both of whom could be denied a day's work due to the 24-hour provision), and employees who have different work hours than others could be difficult. To avoid these situations and ensure workers are informed in all cases before they begin work, the regulation specifies (as a minimum) that employees be informed prior to the commencement of the employee's work activity. Cross-referenced language is easily located within sections 6450-6450.2, and 6784.

Proposed subsection (h) requires that the operator of the property to be treated shall assure that specific notification of the date and time of the start of the fumigation, and anticipated expiration of buffer zones is provided to the other property operator, if the operator of the other property is required to notify his/her employees as specified in (g). This specific fumigation notification shall be provided to the other property operator at least 48 hours prior to starting the fumigation. If the fumigation of an application block does not commence within the time frame specified in 6450.1(a)(2), then a new notification must be provided to the other property operator specified in (e)(3)(A) and (f)(3), but the 48-hour requirement shall not apply unless required by the CAC.

The pre-notification requirement is intended to provide advance information solely to certain neighboring property operators about any restricted materials permits to use methyl bromide on property near their own. This pre-notification is triggered for those neighboring properties situated within 300 feet of the outer buffer zone.

Proposed subsection (i) states that when a school property is within 300 feet of the perimeter of the outer buffer zone, the injection shall be completed 36 hours prior to the start of a school session. School session shall be those times when students are attending scheduled classes. It is

not intended to include times before or after school, or on evenings, weekends, or holidays during which people may be present on the school grounds for educational, extracurricular, administrative, maintenance, or community activities.

DPR determined the 36-hour time frame based upon the time of peak methyl bromide air concentrations. Monitoring data shows that the peak concentrations begin to decrease within 36 hours of fumigant injection. CACs will have the option, as they currently do, to require additional restrictions for applications near schools--such as an extended notification period, larger buffer zones, onsite inspections by CAC staff, and close coordination with school administrators.

Methyl bromide airborne levels should not exceed the DPR target exposure control value for any 24-hour period outside of the outer buffer zone. Consequently, any activities occurring after school or on weekends would not be subject to any airborne levels of exposure concern. In addition, most of these activities will be of short duration and not be equivalent to the entire school day. Requiring the injection to be completed 36 hours prior to the start of a school session adds further protection to the staff and students of an affected school. DPR believes these procedures will allow some fumigation in situations where school grounds are in close proximity and ensure the safety of school occupants and other users of school facilities. In addition, the CAC can condition the permit requirements that are most appropriate based on local conditions.

6450.3 Methyl Bromide Field Fumigation Methods.

Proposed section 6450.3 lists the allowable methods of soil field fumigation, the requirements for each, and some general restrictions.

Proposed subsection (a) lists, on a method-by-method basis, the field soil fumigation methods that will be allowed in California. For each method, DPR has included application rates, equipment specifications, tarpaulin cutting and removal times (if applicable), and restricted entry intervals. An exception to the restrictions of section 6450.3(a) is allowed for experimental research purposes covered under a valid research authorization issued pursuant to section 6260.

The old suggested permit conditions contained 17 different soil fumigation methods. DPR incorporated some of these methods into section 6450.3(a) on a method-by-method basis with all the pertinent requirements for each method contained under the method heading. DPR feels that by doing so, an understanding of, and compliance with, these regulations by the regulated community will be facilitated. Some of the recommended application methods found in the suggested permit conditions have been dropped. Other methods have been reorganized or combined with another method. A detailed discussion of the various methods and applicable monitoring data is found in *Recommendations For Methyl Bromide Buffer Zones For Field Fumigations*.

Application requirements for these methods are partially taken from the old suggested permit conditions. This includes application rates, tractor implements and equipment type and their specifications, the need for an air fan dilution system, and restricted entry intervals. Restricted entry intervals for each method were, as previously noted, taken out of the suggested permit conditions. DPR scientists determined these restricted entry intervals from monitoring results that show declining air concentrations over time and exposure studies during tarpaulin removal. DPR used the change in air concentrations and flux rate over time to determine the restricted entry (reentry) intervals. The University of California reviewed and commented on these data.

Notwithstanding section 6770, proposed subsection (b) would restrict persons entering an application block before the restricted entry interval expires except to perform tarpaulin cutting, removal, and repair as described in section 6784(b)(4) and (5). This proposed action would further reduce potential exposure to fumigation handlers.

6784. Field Fumigation.

Proposed section 6784 includes provisions that were found in the old suggested permit conditions. These provisions include information from: "II. Worker Safety Requirements" and its subsections "A. Restricted Entry Interval and Warning Sign Posting," "B. Pesticide Handler/Field Worker Requirements," "C. Limited Work Schedules," and "D. Tarpaulin Repair."

Current subsection 6784(a) has been relocated to subsection (b)(3)(B).

Proposed subsection (a) states that signs required to be posted in accordance with section 6776(f) shall remain in place until aeration is complete. This is an editorial change to improve clarity to the existing requirement.

The introductory sentence in subsection (b) clarifies that the subsection pertains to field soil fumigations in which methyl bromide is used singly or in combination with chloropicrin or any other pesticide or warning agent pursuant to the fumigation methods described in section 6450.3.

6784(b)(1). Employer Recordkeeping.

The old suggested permit conditions specified that employers must maintain use records for all employees involved in certain activities pertaining to methyl bromide applications and that the employers must maintain the records for two years. DPR has included this requirement in section 6784(b)(1) to ensure employers track employee work hours. DPR's enforcement staff and the CACs would have access to these records to monitor compliance with the work hour restrictions proposed in section 6784(b)(3). The records pertain to all employees involved in application, tarpaulin cutting, tarpaulin repair, and tarpaulin removal activities. The records shall identify the person, work activity(ies), date(s), duration of handling, the U.S. EPA Registration

Number, and the brand name of the methyl bromide product handled.

6784(b)(2). Employee Protection Requirements for Fumigation Handlers.

Proposed subsection (b)(2)(A) specifies that shovelers (employees that cover the edges of the tarpaulins with soil at the end of the treatment rows) are allowed to work only at the ends of the application rows unless respiratory protection specified in subsection (b)(6) is worn. This requirement to work only at the ends of the application rows is found in the old suggested permit conditions on page 5 under "B. Pesticide Handler and Fieldworker Requirements," point 3. However with proper respiratory protection, employees would no longer be restricted to shoveling at the end of the rows.

Proposed subsection (b)(2)(B) requires that two employees be present during introduction of the fumigant and during removal of the tarpaulins.

6784(b)(3). Limited Work Hours and Workdays.

The old suggested permit conditions cover time limits for persons doing various handling activities. These limits are discussed on pages 6 and 7 under "C. Limited Work Schedules." The work hour time limits for these activities vary since 17 different methyl bromide application methods are used. There are time limits for persons performing multiple work tasks, and time limits for tractor drivers and shovelers, and for copilots.

Proposed subsection 6784(b)(3) subdivides limited work hours and workdays into (A) Maximum Work Hours and (B) Maximum Work Hours in a Maximum Three Workdays per Calendar Month.

Proposed subsection (b)(3)(A) is intended, at minimum, to reduce possible subchronic exposure of methyl bromide to or below the target level of 16 ppb (24-hour time-weighted average concentration) to workers. This subsection specifies the maximum employee work hours (Table 1. Maximum Work Hours) in a 24-hour period, during the injection period and during the restricted entry interval, for the various methods of application. DPR scientists have determined that employees, when involved in fumigation handling activities, should be limited to the hours specified in Table 1. The specified hours for some activities may be increased if the methyl bromide application rate is less than the maximum application rate shown in Table 1, or the proper respiratory protection is worn. For example, a handler performing cutting or removal activities are not required to wear a respirator provided their daily work hours do not exceed one or three, respectively. However, if the employee wears a half-face respirator for the entire duration of that particular work task, there are no daily work hour limitations. Additionally, proposed subsection 6784(b)(3)(A)1 would allow employees to perform fumigation-handling

activities that require a half-face respirator with no work hour limitations if a full-face respirator is worn the entire duration of the activity.

Proposed subsection 6784(b)(3)(A)2--Multiple Task Employees--specifies that an employee may work in more than one work task and/or application method in a 24-hour period as long as the total work hours do not exceed the lowest total hours allowed for any one work task or application method performed in Table 1.

For some fumigations, employees will not perform fumigation-handling activities more than three days during the calendar month. Under this situation, exposure to methyl bromide is considered a short-term exposure. The document *Length of Seasonal Exposure of Methyl Bromide Soil Fumigators* is listed in the "Documents Relied Upon" section of this Initial Statement of Reasons. It would not be reasonable for these workers to follow respirator use requirements and be restricted to the work hour limitations for mitigation measures designed to protect against potential subchronic exposure to methyl bromide. Proposed subsection (b)(3)(B) provides an exception to the maximum work hours in (b)(3)(A).

Proposed subsection (b)(3)(B) is intended to reduce possible acute exposure of methyl bromide to or below the target level of 210 ppb to workers who work no more than three days in a calendar month. This subsection specifies the maximum employee work hours (Table 2. Maximum Work Hours in a Maximum Three Workdays per Calendar Month) in a 24-hour period, during the injection period and during the restricted entry interval, for the various methods of application. In the old suggested permit conditions, the employee hour limits varied between 6 and 12 hours. DPR scientists have determined that employees, when involved in fumigant handling activities, should be limited to the hours specified in Table 2. The specified hours for some activities may be increased if the methyl bromide application rate is less than the maximum application rate shown in Table 2, or if proper respiratory protection is worn. Monitoring results from methyl bromide applications and toxicology studies support this determination. DPR has compiled a chart summarizing the application methods, specifications, supporting data sources, and maximum work hours. This chart is contained in the worker safety recommendations entitled, *Recommended Worker Safety Mitigation Measures For Methyl Bromide Soil Fumigation Regulations*, and is listed in the "Documents Relied Upon" section of this Initial Statement of Reasons and is available from DPR.

Also, proposed subsection 6784(b)(3)(B)1 allows employees to perform fumigation-handling activities with no work hour limitations if a half-face respirator is worn the entire duration of the activity.

Proposed subsection 6784(b)(3)(B)2--Multiple Task Employees--specifies that an employee may work in more than one work task and/or application method in a 24-hour period as long as the total work hours do not exceed the lowest total hours allowed for any one work task or application method performed in Table 2.

Proposed subsection 6784(b)(3)(C) will prohibit a fumigation-handling employee from alternating between the workday and work hour requirements specified subsection (b)(3)(A) and (B) unless the employee has not performed fumigation-handling activities during the previous 30 days. As stated above, subsection (b)(3)(B) provides an exception to the maximum work hours employees are allowed since the exposure to methyl bromide is considered short-term exposure when working no more than three days in a calendar month. However, there is concern that a "seasonal" employee, who has been following the work hour requirements in Table 1, may switch to the workday and work hour limitations in Table 2 the following calendar month because of workload fluctuations. The employee could potentially encounter seasonal methyl bromide exposure hazards if the employee had performed fumigation-handling activities within the previous 30 days. This 30-day no work period is required because if an employee is exposed to methyl bromide for a few days during the preceding month, the exposure in the following month could exceed the required three days per calendar month. The operator of the property will be required to include a description of their employee's workday and work hour limitations as part of his proposed work plan. This will assist the CACs in evaluating and conditioning the permit regarding employee work hour requirements.

6784(b)(4). Tarpaulin Cutting and Removal Procedures.

Proposed subsection 6784(b)(4)(A) requires that unsealing of tarpaulins be discontinued at any time if the presence of gas is readily evident. This is evidenced by onset of eye irritation or odor.

Proposed section 6784(b)(4)(B) covers the cutting procedures required in tarpaulin broadcast fumigations. Only mechanical methods (all-terrain vehicle or tractor with a cutting wheel) can be used and tarpaulin panels must be cut lengthwise.

6784(b)(5). Tarpaulin Repair.

The old suggested permit conditions on pages 8 and 9 under the heading "D. Tarpaulin Repair" discuss a "repair response plan" that is sometimes required by CACs in areas where tarpaulins are often damaged and need repair. The plan identifies the responsibilities of the pest control business and/or the permittee with regard to tarpaulin damage detection and repair activities. In proposed section 6784(b)(5)(A) and (B), DPR is requiring property operators to provide a "tarpaulin repair response plan" to the CAC. The tarpaulin repair response plan is to be approved by the CAC in the work site plan and must state with specificity the situations when tarpaulin repair must be conducted. The situations should be based on, but not limited to, hazard to the public, residents or workers; proximity to occupied structures, size of the damaged area(s); timing of damage; feasibility of repair; and environmental factors such as wind speed and direction. In addition, DPR has added a requirement in (5)(C) that a certified applicator of the licensed pest control business, using a testing device as specified by the pesticide product labeling, must test the ambient air in the areas in which tarpaulins are to be repaired. Self-contained breathing apparatus (SCBA) must be worn when conducting these tests. During repair

activities, employees must wear respiratory protection if there is five ppm or greater methyl bromide concentration in the work area. If there is less than a five ppm methyl bromide concentration, respiratory protection is not required, but employees involved in tarpaulin repair activities are limited to one work hour in a 24-hour period except as provided in section (6).

6784(b)(6). Respiratory Protection Requirements.

Currently in the emergency regulation, subsection 6784(b)(7) includes a maximum work hour exemption. "Table 1. Maximum Work Hours" lists maximum work hours in a 24-hour period for various types of fumigation handling activities. Fumigation handlers are exempt from these restrictions if they wear NIOSH-certified respiratory protection specifically recommended for use in atmospheres containing less than five ppm of methyl bromide for the entire duration of the fumigation handling activities. Because of the workday and work hour limitations proposed in subsection (b)(3), this exemption is no longer applicable.

Proposed subsection 6784(b)(6) would require fumigation handlers to wear NIOSH-certified respiratory protection specifically recommended by the manufacturer for use in atmospheres containing less than five ppm methyl bromide, if required by section 6784. Fumigation handlers would be required to wear the required respiratory protection during the entire duration of the fumigation-handling activity and any requirements for respiratory protection on the product label shall not be superceded by this regulation. NIOSH-approved, air-supplying respiratory protection could be used in lieu of chemical cartridge respirators.

DPR is relying on historical air monitoring data to support the determination that air concentrations of methyl bromide will be acceptable. After extensive field studies, DPR concluded that the six allowed methods of application resulted in acceptable levels of methyl bromide exposure. Additionally, U.S. EPA-approved label requirements address application problems, such as leaking canisters. Chloropicrin is included as a warning agent in all methyl bromide products used for field fumigation. Chloropicrin is a tear gas-like agent and, when used with methyl bromide, its presence indicates potentially unsafe concentrations of methyl bromide. Labels require people to immediately leave the area if chloropicrin is detected and to don an SCBA to repair the problem, such as leaking containers.

After consultation with DPR staff, representatives from 3M Company's Occupational Health and Environmental Safety Division worked with Trical, Inc. (a methyl bromide product registrant and a DPR-licensed pest control business) to develop an alternative mitigation measure that would allow an exemption from the work hour limits if fumigation handlers wear NIOSH-certified respirator protection. 3M has conducted testing on their model 60928 cartridge and determined that the cartridge provided 24 hours of service without any detection of a five percent maximum ambient concentration of methyl bromide seeping through the cartridge. 3M amended its respirator packaging instructions to allow for this use and NIOSH has granted approval for certain organic vapors.

The 3M cartridge instructions read:

"The 3M 60928 organic vapor/acid gas cartridge with P100 particulate filter is NIOSH approved for certain organic vapors, acid gases and both oil and non-oil aerosols. The NIOSH approval number for the 3M 6000 series half facepiece and the 60928 cartridge is TC-84A-0284. 3M recommends that when used with the 3M 6000 Series half facepiece, the 60928 cartridges may be used for one day's use against methyl bromide for concentrations less than 5 ppm.

Please consult the user instructions and approval label for other restrictions on the use of this respirator and cartridge."

The labeling for the 3M 60928 Organic Vapor/Acid Gas Cartridge/P100 Filter contains a paragraph that reads, "NIOSH approved for use against certain organic vapors, chloride, sulfur dioxide or hydrogen fluoride or hydrogen sulfide (escape) and particulates when used with the facepieces and adapters as stated above."

NIOSH approves respirators for certain classes of substances, not for a specific chemical like methyl bromide. NIOSH tested the filter/cartridge combination against organic vapor, and for acid gasses and particulates. NIOSH uses carbon tetrachloride (CCl_4) for the organic vapor test. If it passes this test, which is a challenge atmosphere of 1,000 ppm carbon tetrachloride (CCl_4), it is certified for organic vapor protection. The manufacturer then makes the recommendations for use and accepts the liability for such recommendations. 3M made this recommendation after it developed and tested the cartridge/filter. See 3M Technical Data Bulletin #146, February 2001, in the "Documents Relied Upon" section of this Initial Statement of Reasons.

The Permissible Exposure Limit (PEL) for methyl bromide is five ppm. NIOSH has told DPR that it has no recommendations for respiratory protection below the PEL and that 3M assumes liability for this recommendation. NIOSH feels that there is no need for a respirator if the PEL is below five ppm. No other state or federal agency requires a respirator for methyl bromide use under the five ppm PEL.

DPR understands that, so far, 3M Company is the only firm to have tested their NIOSH-certified respirators against sub-PEL methyl bromide levels. Other companies have similar or identical products and may also engage in testing their efficacy against sub-PEL methyl bromide levels. These other products could be used once the company provides such information to DPR and issues specific written instructions with their cartridges concerning use in sub-PEL methyl bromide atmospheres. DPR does not endorse any particular product.

ALTERNATIVES TO THE PROPOSED REGULATORY ACTION (GOVERNMENT CODE SECTION 11346.2(b)

DPR has not identified any feasible alternatives to the proposed regulatory action that would lessen any possible adverse economic impacts, including any impacts on small businesses, and invites the submission of suggested alternatives.

As required by Chapter 418 (Senate Bill 1082, Statutes of 1993), every California Environmental Protection Agency (Cal/EPA) board, department, or office must, prior to adopting any "major regulation," perform a cost analysis of alternatives to the proposed regulation that may be submitted as comments during the public comment period, and determine whether there is a less costly, but equally effective alternative. A "major regulation" is any proposed regulation that will have a potential cost to California business enterprises in any amount exceeding $10 million in any single year."

For the regulation noticed on January 10, 2000, DPR had determined that it was a "major regulation" as defined in Health and Safety Code section 57005. DPR made its economic impact determination based upon an economic impact assessment performed by Cal/EPA's Agency-Wide Economic Analysis Unit. The Cal/EPA economic impact assessment estimated the first-year cost of the regulation at around $16 million. Due to data limitations, several strong assumptions were required in order to develop adjustments to the estimate. The economic impact assessment addressed these assumptions and the adjustments made to the estimates, as well as the overall reliability of the estimate.

After noticing the originally proposed text for the initial regulatory proposal on January 10, 2000, DPR received and considered many comments and subsequently incorporated some of them into modified texts. Comments received during the first and second 15-day public comment periods for the modified texts confirmed that the changes would make the regulations less burdensome to affected private persons or businesses than the regulations as originally proposed. The modified regulations became effective in January 2001.

Cal/EPA's Agency-Wide Economic Analysis Unit prepared a second economic impact assessment for the methyl bromide regulations DPR noticed on December 14, 2001, and subsequently adopted in April 2002. The amendments adopted at that time substantially mitigated the impact of the previous regulations to directly affected businesses.

The second Cal/EPA economic assessment indicated that two provisions of the regulations noticed on December 14, 2001, would reduce compliance costs to those applying methyl bromide by reducing the number of treatment days required. The regulation would allow inner buffer zones to extend across roadways and exempt workers equipped with NIOSH-certified respirators from restrictions on the time they spend applying methyl bromide. Data limitations precluded an estimate of the amount of reduced compliance costs.

The currently proposed regulations would require the use of respiratory protection, in most cases, if an employee who performs fumigation handling activities, works more than three days in a calendar month. The use of respiratory protection for potentially all handlers of methyl bromide will trigger the requirements of 3 CCR section 6738(h). Since methyl bromide handlers will, in most cases, be required to wear NIOSH-approved respiratory protection, the employers must fulfill the section 6738(h) requirements, including having written operating procedures for selecting, fitting, cleaning, and sanitizing, inspecting and maintaining the equipment. Though the tractor driver and the copilot of an methyl bromide application crew may already be required to wear respiratory protection in some instances (hence already in compliance with section 6738), the proposed regulations draw all other associated crew members (i.e., shovelers, tarpaulin removers, etc.) into the respirator requirements of section 6738(h). This will require an additional cost in training and outfitting these workers.

No other less burdensome alternatives were received, identified, or evaluated in response to those proposed regulations.

When DPR noticed its proposed regulations on January 10, 2000, it indicated that one alternative would be a ban on the agricultural use of methyl bromide. Some public interest groups advocate such a ban. However, the economic effects could be devastating. The CDFA conducted an impact assessment on the economic effects resulting from a ban on the agricultural use of methyl bromide. In the CDFA document *Methyl Bromide: An Impact Assessment*, which was available on the CDFA Web site at that time, it was estimated that a $248.3 million revenue loss to California's agricultural sector would result if methyl bromide became unavailable for preplant soil fumigation on a variety of crops.

Another alternative would be to not readopt the regulations since they were voided by the judge. Some people may question the need for readoption of the methyl bromide regulations when: (1) domestic production of methyl bromide has ended, (2) methyl bromide use is to be phased out by the federal government by 2005, and (3) extensive ongoing research is being conducted in an effort to find satisfactory methyl bromide substitutes. However, this is not a satisfactory option for DPR for the following reasons. First, DPR was ordered by a California Superior Court in 1999 to adopt new methyl bromide regulations. Second, DPR's risk assessment, monitoring data, and computer modeling at that time (1999) indicated that additional measures to mitigate methyl bromide exposures were needed. And third, public interest groups expressed a strong interest in both DPR's adoption of new methyl bromide regulations and in playing a role in developing the text of the proposed regulations.

DPR conducts human health risk assessments in the form of RCDs to evaluate the potential effects from exposures. When these RCDs indicate unacceptable cancer risks or inadequate margins of exposure (MOE), a spectrum of approaches are available to apply risk mitigation measures. These may include modifications to permit conditions, suspension or cancellation of product registrations, voluntary modifications of labeled use conditions by the registrant,

additional use restrictions required by regulation (as in the present case), etc. Likewise, if the human health risk assessment indicates adequate risk levels or adequate MOE, no risk mitigation actions will be required or adopted. DPR has compared the risk reduction of the proposed regulatory action for methyl bromide with other risk reduction measures adopted by DPR and other agencies. These other risk reduction measures are discussed below.

In 1987, DPR (then part of the CDFA) completed an RCD on the pesticide Cyhexatin. This RCD indicated that MOE for developmental effects were well below the benchmark value of 100. Partially as a result of discussions with the Department regarding possible cancellation or suspension action, the registrant voluntarily withdrew the California registrations of Cyhexatin, and the registrations were cancelled in 1988.

In 1997, DPR completed an RCD on the pesticide Propoxur. This RCD indicated that the MOE for neurotoxic effects were above the benchmark of 100 and the risks of carcinogenic effects met the conventional benchmarks of 1×10^{-6} for non-occupational exposure and 1×10^{-5} for occupational exposure. As a result, additional risk reduction measures were not necessary and were not adopted.

In 1990, high ambient air levels of the pesticide 1,3-dichloropropene (Telone II) were measured. The measured air levels indicated cancer risks well in excess of the conventionally accepted benchmarks. As a result, the Department suspended all permits for the use of Telone II in California. Limited use was reinstituted in 1994 with additional mitigation measures agreed to by the registrant. These measures included application limits, changes to application methods, and the imposition of buffer zones.

Regarding three risk reduction actions undertaken by other governmental agencies, the Office of Pesticide Programs of the U.S. EPA generally assesses risk and sets forth required risk reduction measures in their Reregistration Eligibility Documents (REDs). In 1991, U.S. EPA initiated a project to find regulatory solutions for pesticides posing acute health risks to agricultural workers. Based primarily on human incident data, U.S. EPA identified five pesticides that warranted accelerated action. In 1993, U.S. EPA met with the registrants of the five pesticides and requested voluntary risk reduction measures. In 1993, the registrant of mevinphos (one of the five pesticides) submitted proposed risk reduction measures, but U.S. EPA determined that the measures were inadequate. In 1994, based on an evaluation of the toxicological database for mevinphos, as well as human incident data, U.S. EPA determined that mevinphos was unsafe for any use. U.S. EPA was prepared to suspend all registrations; however, the registrant requested voluntary cancellation.

In 1998, U.S. EPA issued a RED for the fumigant aluminum phosphide. The RED determined that the short- and intermediate-term inhalation risks were acceptable (MOE greater than 100) if specific protective (risk reduction) measures were followed. These measures were specified in the RED and were required for aluminum phosphide to be eligible for reregistration. These

measures included notification of authorities, requirements for certification of applicators, placarding of fumigated areas, use of personal protective equipment, establishment of a 500-foot buffer zone around fumigated structures, institution of additional monitoring, notification of local residents, etc.

In 1999, U.S. EPA issued a RED for the fungicide Folpet. In the RED, U.S. EPA determined that the only unacceptable risks or inadequate margins of safety were for Folpet handlers, particularly mixers/loaders who came into contact with Folpet while adding it to paint during manufacture. The MOE for this activity was less than 100. As a condition for reregistration, U.S. EPA required risk reduction through the use of gloves and dust/mist respirator or equivalent engineering controls for workers adding the wettable powder to paints and stains during the manufacturing process.

IDENTIFICATION OF ANY SIGNIFICANT ADVERSE ENVIRONMENTAL EFFECT THAT CAN REASONABLY BE EXPECTED TO OCCUR FROM IMPLEMENTING THE PROPOSAL

Under the State's certified pesticide regulatory program, DPR is required to prepare a public report when the Director proposes to adopt, amend, or repeal a regulation of the regulatory program, and allow 45 days for the public to review each proposal (Title 3, CCR, section 6110). Section 6110 implements Public Resources Code section 21080.5 (the portion of CEQA addressing certified regulatory programs). The Secretary of the Resources Agency determined that section 6110 satisfies the requirements of Public Resources Code section 21080.5 and Title 14, CCR, section 15252 because the Secretary certified the pesticide regulatory program, which includes section 6110. Therefore, the section 6110 report is the document DPR is to use as a substitute for an EIR or negative declaration. In this rulemaking, the public report is combined with the Initial Statement of Reasons, and the combined document is identified as the "Initial Statement of Reasons and Public Report."

Under section 6110, in respect to environmental effects, the report is to include a statement of any significant adverse environmental effect that can reasonably be expected to occur, directly or indirectly, from implementing the proposal. If DPR identified any significant adverse environmental effect, the report is to include a statement of any reasonable mitigation measures that are available to minimize any significant adverse environmental impact and a statement and discussion of reasonable alternatives that would reduce any significant environmental impact.

When proposing to register pesticide products, DPR must consider environmental effects of the proposal and prepare a public report (3 CCR section 6254). Since methyl bromide and chloropicrin products have been registered by DPR for many years and are currently registered, their use is allowed in California in accordance with label directions, existing applicable regulations, and permit conditions imposed by CACs. Such site-specific permits are required

when a person wants to fumigate soil in fields with methyl bromide and chloropicrin (3 CCR section 6400, et seq.).

When a CAC receives an application for a permit for the use of methyl bromide and chloropicrin, the CAC must determine if the proposed use at a specific site could have a significant adverse effect on the environment (3 CCR sections 6420-6436). Methyl bromide and chloropicrin have been injected into the soil for many years for preplant field soil fumigation in the production of agricultural commodities under CAC permits without any significant adverse effects on California's soil, water, air, plants, fish, or wildlife.

Without the proposed regulations, soil field fumigation using methyl bromide, singly or in combination with chloropicrin, could occur in accordance with label directions, applicable existing non-emergency regulations (since the emergency regulations will expire), and CAC-imposed permit conditions. The proposed rulemaking does not permit use of these products, but, rather, provides some of the requirements to be followed if a CAC authorizes soil field fumigation use at a particular site under a CAC-issued permit.

At DPR's request, ARB conducted air sampling for methyl bromide in Monterey and Santa Cruz counties during the fall of 2001. The air monitoring coincided with DPR's new regulations. DPR reviewed the 2001 monitoring data to determine whether the new restrictions aimed at mitigating short-term exposures were effective. The monitoring data show that levels of methyl bromide in ambient air have declined. In addition, the continuing federal phaseout of methyl bromide, with a 50 percent reduction in production and importation this year and another 33 percent in 2003, is expected to have an increasing impact on reducing the amount of methyl bromide used for soil fumigation in California.

Methyl bromide occurs naturally in the air. This natural occurrence is in concentrations much lower than those found in areas near agricultural use of methyl bromide. While there are temporary increases in levels of methyl bromide in the air during soil field fumigations, the proposed regulations provide mitigation measures so that acute or subchronic (seasonal) exposures typically will not exceed target levels that provided an adequate margin of safety for human exposure. No physical change in the environment will result from the proposed regulations which themselves are mitigation measures, and no significant adverse environmental effect to California's air, soil, water, plants, fish, or wildlife can reasonably be expected to occur from implementing the proposal. Therefore, no alternatives or mitigation measures are proposed to lessen any significant adverse effects on the environment.

EFFORTS TO AVOID UNNECESSARY DUPLICATION WITH FEDERAL REGULATIONS

The proposed regulatory action does not duplicate or conflict with federal regulations because there are no federal regulations contained within the Code of Federal Regulations that address

this issue. Only the U.S. EPA-approved product labels address soil field fumigation use of methyl bromide.

CONSULTATION WITH OTHER AGENCIES

DPR has consulted with CDFA during the development of the text of proposed regulations as specified in FAC section 11454, and the February 6, 1992, Memorandum of Agreement which was developed as provided in section 11454.2. Copies of correspondence with CDFA are contained in the rulemaking file.

DPR has also consulted with the Office of Environmental Health Hazard Assessment, Department of Industrial Relations, ARB, County Air Pollution Control District, University of California, and the California Agricultural Commissioners and Sealers Association.

DOCUMENTS RELIED UPON

Note that documents 1-24 are contained within the rulemaking files for OAL File No. 00-1031-06S and OAL File No. 02-0222-03C and were documents relied upon for DPR's regulations that became effective January 14, 2001, and April 8, 2002, respectively.

1. Judgment Granting Peremptory Writ of Mandate. Superior Court of the State of California for the County of San Francisco. Case No. 996187. July 14, 1999.

2. Methyl Bromide Proposed Soil Injection Fumigation Permit Conditions.

3. Segawa, Randy; Bruce Johnson; Terrell Barry. Recommendations for Methyl Bromide Buffer Zones for Field Fumigations. Memorandum to John Sanders, January 2000. Department of Pesticide Regulation.

4. Segawa, Randy; Bruce Johnson; Terrell Barry. Summary of Off-Site Air Monitoring for Methyl Bromide Field Fumigations. Memorandum to John Sanders, January 2000. Department of Pesticide Regulation.

5. Gibbons, Dennis; Thomas Thongsinthusak. Recommended Worker Safety Mitigation Measures for Methyl Bromide Soil Fumigation Regulations. Memorandum to Chuck Andrews, January 7, 2000. Department of Pesticide Regulation. HSM-00014.

6. Johnson, Bruce, Terrell Barry, and Pamela Wofford. Workbook For Gaussian Modeling Analysis of Air Concentration Measurements (EH99-03). Department of Pesticide Regulation, Sacramento. September 1999.

7. Methyl Bromide Risk Characterization Document For Inhalation Exposure (Draft). Department of Pesticide Regulation, Medical Toxicology, Worker Health and Safety, and Environmental Monitoring and Pest Management Branches. Sacramento. October 15, 1999.

8. Enforcement Letters ENF 96-020 (April 10, 1996) and 96-047 (September 20, 1996). Updates to the Suggested Permit Conditions for Soil Injection, Greenhouse, and Tarped Potting Soil. Department of Pesticide Regulation, Pesticide Enforcement Branch.

9. Methyl Bromide: An Impact Assessment, Executive Summary. California Department of Food and Agriculture. (http://www.cdfa.ca.gov/newsinfo/publications/mbr.html).

10. Pre-notice Assessment of the Economic Impacts of the Proposed DPR Regulation Governing Field Applications of Methyl Bromide. California Environmental Protection Agency, Agencywide Economic Analysis Unit, Air Resources Board. January 2000.

11. Economic Implications of the Methyl Bromide Phaseout, U.S. Department of Agriculture, Economic Research Service, Agriculture Information Bulletin Number 756. February 2000.

12. Nazaroff, William, Ph.D. Review of Proposed Regulations for Methyl Bromide Field Fumigations, University of California, Berkeley, March 4, 2000.

13. Review of Draft Methyl Bromide Regulation and Buffer Zone Dispersion Modeling, California Air Resources Board, March 17, 2000.

14. Yates, Dr. Scott R. Review of "Summary of Off-site Air Monitoring For Methyl Bromide Field Fumigations," "Recommendations for Methyl Bromide Buffer Zones for Field Fumigations," "Evaluation of Charcoal Tube and SUMMA Canister Recoveries from Methyl Bromide Air Sampling," and Text of Proposed Regulations. University of California, Riverside. March 17, 2000.

15. Cohen, Professor Yoram. Review of DPR's Proposed Methyl Bromide Regulations for Field Fumigation and Supporting Documents. University of California, Los Angeles. March 22, 2000.

16. Methyl Bromide Risk Characterization in California, National Research Council. May 2000.

17. Letter From Paul Helliker, Director of DPR, to Dr. Charles H. Hobbs, Chair, Subcommittee on the Review of the Risk Assessment for Methyl Bromide. May 5, 2000.

18. Johnson, Bruce; Randy Segawa. Re-analysis of Decline Rates for Methyl Bromide Flux Rates and Buffer Zone Durations. Memorandum to John Sanders, May 2000. Department of Pesticide Regulation.

19. Biermann, Heinz W.; Terrell Barry. Evaluation of Charcoal Tube and SUMMA Canister Recoveries for Methyl Bromide Air Sampling. Report EH 99-02. Department of Pesticide Regulation. June 1999.

20. Gibbons, Dennis; Thongsinthusak, Thomas. Revised Work Hours for Methyl Bromide Soil Fumigation Regulations. Memorandum to Chuck Andrews, May 9, 2000. Department of Pesticide Regulation, Worker Health and Safety. HSM-00015.

21. Air Toxic Hot Spot Program Risk Assessment Guidelines: Part 1. The Determination of Acute Reference Exposure Levels for Airborne Toxicants. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, March 1999.

22. Methyl Bromide Risk Characterization Document for Inhalation Exposure, Department of Pesticide Regulation, Medical Toxicology, Worker Health and Safety, and Environmental Monitoring and Pest Management Branches. Sacramento. February 2002.

23. Use Recommendations for 3M 60928 Cartridge/Filter. 3M Technical Data Bulletin #146, February 2001.

24. Consultation on Draft Regulation on Methyl Bromide Field Fumigations - Public Roadways. California Environmental Protection Agency, Air Resources Board, Agency-Wide Economic Analysis Unit. October 29, 2001.

25. Judgment Granting Writ of Mandate. Superior Court of the State of California for the County of San Francisco. Case No. 318270. April 8, 2002.

26. Ambient Air Monitoring for Methyl Bromide and 1,3-Dichloropropen in Monterey and Santa Cruz Counties--Fall 2001. Project No. P-01-004. Air Resources Board. Operational Planning and Assessment Section, Quality Management Branch, Monitoring and Laboratory Division. March 29, 2002.

27. The Guidance Manual: Methyl Bromide (In Combination With Chloropicrin) - Field Soil Fumigation. Department of Pesticide Regulation. January 2001.

28. Methyl Bromide Risk Characterization Document Inhalation Exposure Addendum to Volume I. Department of Pesticide Regulation, Medical Toxicology Branch. Sacramento. February 3, 2003.

29. Lim, Lori. Response to Comments from Methyl Bromide Subchronic Regulatory Level Workshop on February 26, 2003. Memorandum to Gary Patterson, May 2003.

30. Thongsinthusak, Thomas; Joseph P. Frank. Mitigation Measures for Seasonal Exposures of Agricultural Workers to Methyl Bromide. Memorandum to Chuck Andrews, May 22, 2003. Department of Pesticide Regulation, Worker Health and Safety. HSM-03012.

31. Johnson, Bruce; Lin Ying Li. Calculation of a Tolerance Interval for a Township Limit on Methyl Bromide Use to Control Subchronic Exposure. Memorandum to Randy Segawa, July 11, 2003. Department of Pesticide Regulation, Environmental Monitoring.

32. Segawa, Randy; Johnson, Bruce; Lin Ying Li; Walters, Johanna. Evaluation of Ambient Air Monitoring and Township-Month Use Period Distribution of Methyl Bromide for Subchronic Exposure Assessments. Memorandum to John S. Sanders, July 24, 2003. Department of Pesticide Regulation, Environmental Monitoring.

33. Frank, Joseph P. Statistical Analyses to Determine a Use Cap for Limiting Seasonal Ambient Exposure to Methyl Bromide. Memorandum to Randy Segawa, June 6, 2003. Department of Pesticide Regulation, Worker Health and Safety. HSM-03015.

34. Frank, Joseph P. Length of Seasonal Exposure of Methyl Bromide Soil Fumigators. Memorandum to Randy Segawa, June 6, 2003. Department of Pesticide Regulation, Worker Health and Safety. HSM-03016.

35. Science, Volume. 267, February 17, 1995. A Net Sink of Atmospheric CH_3Br in the East Pacific Ocean.

36. Carter, Colin; Chalfant, James; Goodhue, Rachael. Economic Analysis of the Effects of the January 2001 DPR Methyl Bromide Fumigation Regulations on the California Strawberry Industry. University of California, Davis. March 21, 2002.

37. Consultation on Draft Regulation on Methyl Bromide Field Fumigations. California Environmental Protection Agency, Air Resources Board, Agency-Wide Economic Analysis Unit. September 2003.